DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

10/1/97

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PURGED

September 18, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 63

Robert J. Rose, M.D.
President
Physician Engineered Products, Inc.
198 Kearsage
North Conway, New Hampshire 03860

Dear Dr. Rose:

During an inspection of your facility located at Park Rapids, MN, on September 4, 1997, our investigator determined that your firm manufacturers infant phototherapy systems. Infant phototherapy systems are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in manufacturing these devices are not in conformance with the Good Manufacturing Practice regulations (GMPs) as specified in Title 21, Code of Federal Regulations, Part 820 as follows:

1. The complaint handling system fails to identify and capture product failures entering through the service department.

2. The fluorescent lights used in the Bili system are not tested as incoming components, during manufacture, or at finished device testing.

For more details on objectionable conditions please refer to the September 4, 1997, form FDA-483.

This letter is not intended to be an all-inclusive list of the deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of violations identified by FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include but are not limited to product seizure, company injunction and/or civil penalties. Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to identify and correct any underlying systems problems necessary to ensure that similar violations do not recur. If corrective action cannot be completed within 15 working days state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TPN/ccl

xc: Larry Sundsrud
CEO/Physician Engineered Products, Inc.
420 West Second Street, HC 06 Box 17
Park Rapids, MN 56470